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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/796,396	03/09/2004	Mimi L. Quan	PH7493 NP	1885

23914 7590 04/15/2005

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EXAMINER

DESAI, RITA J

ART UNIT

PAPER NUMBER

1625

DATE MAILED: 04/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/796,396

Applicant(s)

QUAN ET AL.

Examiner

Rita J. Desai

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 11-23 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-9 is/are allowed.
- 6) ☒ Claim(s) 10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>9/04/11/04/7/04/5/</u> . | 6) <input type="checkbox"/> Other: ____.  |

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## DETAILED ACTION

### *Inventorship*

In view of the papers filed 5/12/04, it has been found that this nonprovisional application, as filed, through error and without deceptive intent, improperly set forth the inventorship, and accordingly, this application has been corrected in compliance with 37 CFR 1.48(a). The inventorship of this application has been changed by

Adding

Dietmar Seiffert and

Robert Knabb

Hence the inventors now are

identified application should be changed from Mimi L. Quan, Cailan Wang, Jinglan Zhou, Jon J. Hangeland to Mimi L. Quan, Cailan Wang, Jinglan Zhou, Jon J. Hangeland, Dietmar A. Seiffert and Robert M. Knabb.

The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of Office records to reflect the inventorship as corrected.

Claims pending 1- 23.

*Election/Restrictions*

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Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-7 in part, drawn to compounds and pharmaceutical compositions wherein X1-X4 are all CR1, CR2, CR3, wherein R1, R2, R3, R16 are non hetero ring containing, L1 is a bond, A is a phenyl, L2 is a bond, CH2 or an O, B is a phenyl, R4 is a phenyl and R5 is an alkyl, R13, R14 and R15 do not form another fused or spiro ring classified in class 546, subclass 152. An election of e.g. 39 page 91 was elected and the examiner has made the following group based on the fair interpretation of the chemical and legal equivalence.
- II. Claims 1-6 in part, drawn to compounds and pharmaceutical compositions wherein one of the X1-X4 is a N, classified in class 546, subclass 122. A further election of a single disclosed species is required. May be subject to further restriction.
- III. Claims 1-6 in part, drawn to compounds and pharmaceutical compositions wherein the variables R1-R15 and X1-X4, L1, L2, A and B are different than the above two groups, classified in various classes and subclasses. A further election of a single disclosed species is required.
- IV. Claims 8-10, 13, 14 drawn to methods of treating thromboembolic disorders, classified in class 514 and various subclasses.
- V. Claims 11 and 12, drawn to treating an inflammatory disease, classified in class 514 and various subclasses.

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VI. Claims 15-19 , drawn to complex compositions of the pharmaceutical compounds and other agents, classified in class 514 and various subclasses.

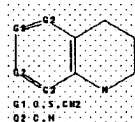
VII. Claims 20- 23 , drawn to an article of manufacture, classified in class 424 and various subclasses.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have completely different structures.

The compounds range from tetrahydro quinolines to naphthydrins with various substituents.

A preliminary search on the core gave numerous iterations and did not run to completion..



=> s11

SAMPLE SEARCH INITIATED 12:21:43 FILE 'REGISTRY'

SAMPLE SCREEN SEARCH COMPLETED - 134444 TO ITERATE

0.7% PROCESSED 1000 ITERATIONS 50 ANSWERS

INCOMPLETE SEARCH (SYSTEM LIMIT EXCEEDED)

SEARCH TIME: 00.00.01

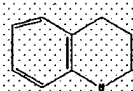
FULL FILE PROJECTIONS: ONLINE \*\*INCOMPLETE\*\*

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BATCH \*\*INCOMPLETE\*\*

PROJECTED ITERATIONS: EXCEEDS 1000000

When the examiner narrowed it down to



it still did not run to completion!

=> s 13

SAMPLE SEARCH INITIATED 12:24:16 FILE 'REGISTRY'

SAMPLE SCREEN SEARCH COMPLETED - 63932 TO ITERATE

1.6% PROCESSED 1000 ITERATIONS 50 ANSWERS

INCOMPLETE SEARCH (SYSTEM LIMIT EXCEEDED)

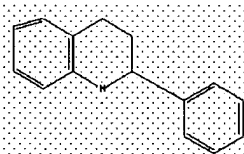
SEARCH TIME: 00.00.01

FULL FILE PROJECTIONS: ONLINE \*\*INCOMPLETE\*\*

BATCH \*\*INCOMPLETE\*\*

PROJECTED ITERATIONS: EXCEEDS 1000000

When the examiner narrowed it further it still gave numerous iterations.



=> s 15

SAMPLE SEARCH INITIATED 12:30:51 FILE 'REGISTRY'

SAMPLE SCREEN SEARCH COMPLETED - 19004 TO ITERATE

5.3% PROCESSED 1000 ITERATIONS 50 ANSWERS

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INCOMPLETE SEARCH (SYSTEM LIMIT EXCEEDED)

SEARCH TIME: 00.00.01

FULL FILE PROJECTIONS: ONLINE \*\*COMPLETE\*\*

BATCH \*\*COMPLETE\*\*

PROJECTED ITERATIONS: 371828 TO 388332

Thus applicants core is not novel and is considered a burdensome search.

Inventions I-III and IV and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case applicants own admission that the compounds can treat thromboembolic disorders and also inflammatory disorders shows that it can be used in a materially different way. Also the process of treating thromboembolic disorders and also inflammatory disorders can be done by other pharmaceutical drugs.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II-VII, restriction for examination purposes as indicated is proper.

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During a telephone conversation with Ms. Jing Belfield on 4/ 12/05 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-7 in part. Affirmation of this election must be made by applicant in replying to this Office action. Claims 8- 23 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicants are required to cancel the non elected subject matter in their response.

Applicants preserve their right to file a divisional on the cancelled non-elected subject matter without prejudice in due course.

If applicant 's traverse on the grounds that the inventions are not patentably distinct, applicants should submit evidence or identify such evidence now of record showing the groups to be obvious variants or clearly admit on the record that this is the case. In either instance if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 USC 103 of the other invention.

The closest prior art with R4 being a phenyl and R5 being an alkyl are not the biphenyls, i.e. the B portion of the compounds of the invention is absent.



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Since the compounds limited to the scope of the elected group are found to be allowable the method of treating Group IV is being rejoined.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim recites or F) other procedures in which blood is exposed... is unclear since it does not clear define "what " these other " procedures are.

***Conclusion***

The claim 1-10, limited in scope to the elected group are found to be allowable over the prior art.

If applicants amend the claims to the elected group and overcome the 112 issues, the elected claims would be allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rita J. Desai whose telephone number is 571-272-0684.

The examiner can normally be reached on Monday - Friday, 9:30 am to 6:00 pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Rita J. Desai  
Primary Examiner  
Art Unit 1625

R.D.  
April 13, 2005

  
4/13/05